



Office of the City Attorney

January 14, 2005

The Honorable Lester M. Crawford, D.V.M., Ph.D.
Commissioner of the Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857

Re: Request for Status on Advisory Opinion (21 CFR 808.5) or Exemption (21 CFR 808.1, 808.10); Regarding Automatic External Defibrillators

Dear Dr. Crawford:

On behalf of the City of Arlington, Texas we request the status of our request for Advisory Opinion from the Commissioner of the Food and Drug Administration (July 27, 2004).

Sincerely,

A handwritten signature in cursive script that reads 'Ivan Bland'. To the right of the signature, the initials 'IB/blj' are written.

Ivan Bland
Assistant City Attorney

IB/blj

cc: Division of Dockets Management (HFA 305)
Food and Drug Administration
Department of Health and Human Services
5600 Fishers Lane, Rm. 1061
Rockville, Maryland 20852

Jim Self, Fire Battalion Chief, Medical Operations, Mail Stop #04-0260
Jay B. Doegey, City Attorney

July 27, 2004

The Honorable Lester M. Crawford, D.V.M., Ph.D.
Commissioner of the Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857

Re: Request for Advisory Opinion (21 CFR 808.5) or Exemption (21 CFR 808.1, 808.10); Regarding Automatic External Defibrillators

Dear Dr. Crawford:

On behalf of the City of Arlington, Texas we request an opinion from the Commissioner of the Food and Drug Administration or a designee with respect to:

Whether the City of Arlington needs to follow FDA formal procedures for an advisory opinion or for an exemption to preemption of regulation for any of the following.

City regulation requiring:

Automatic External Defibrillators (AEDs) in Health Facilities

AEDs in buildings with 1000 person or over occupancy limits, or

Registration

Sample ordinances for each scenario are attached. It appears that ordinances such as those attached are not regulated by the federal government since they do not relate to *the safety or effectiveness of the device* (21 U.S.C. § 360k(a) (2)).

On behalf of the City of Arlington, I respectfully request a determination that an advisory opinion or exemption is not needed in accordance with FDA regulations.

The Honorable Lester M. Crawford, D.V.M., Ph.D.

July 27, 2004

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Respectfully submitted,

CITY ATTORNEY OF THE
CITY OF ARLINGTON, TEXAS

BY: SI

IVAN BLAND

State Bar No. 02452400

Assistant City Attorney

JAY B. DOEGEY

State Bar No. 05942600

City Attorney

Post Office Box 231

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(817) 459-6878

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ATTORNEYS FOR

CITY OF ARLINGTON, TEXAS

Enclosure

cc: Division of Dockets Management (HFA 305)
Food and Drug Administration
Department of Health and Human Services
5600 Fishers Lane, Rm. 1061
Rockville, Maryland 20852

David Stapp, Fire Battalion Chief, Medical Operations, Mail Stop #04-0260
Jay B. Doegey, City Attorney

ORDINANCE NO. _____

AN ORDINANCE ADOPTING THE **"AUTOMATIC EXTERNAL DEFIBRILLATOR (AED)"** CHAPTER OF THE CODE OF THE CITY OF ARLINGTON, TEXAS 1987; PROVIDING FOR A FINE OF UP TO \$2,000 FOR EACH VIOLATION OF THIS ORDINANCE; PROVIDING THIS ORDINANCE BE CUMULATIVE; PROVIDING FOR SEVERABILITY, GOVERNMENTAL IMMUNITY, INJUNCTIONS, PUBLICATION AND BECOMING EFFECTIVE TEN DAYS AFTER FIRST PUBLICATION

- WHEREAS, In 1999, the Texas Legislature passed legislation authorizing public access to Automatic External Defibrillators (AEDs) now codified as Chapter 779 of the Texas Health and Safety code which stated that more than 1,000 people die every day from cardiac arrest, although as many as ninety (90%) percent could be saved if defibrillators reached them in time and each minute that passes before defibrillation decreases a victim's chances for survival by about ten (10%) percent and few defibrillation attempts are successful after ten (10) minutes; and
- WHEREAS, The American Heart Association has also determined that a key way to improve survival rates from sudden cardiac arrest is to reduce the time to deliver defibrillation; and
- WHEREAS, The American Heart Association reports new technology has resulted in the availability of AEDs which are safe and effective for use by lay persons; and
- WHEREAS, Chapter 779 of the Texas Health and Safety Code requires a person or entity that acquires an AED to promptly notify the local emergency medical services provider and provide information on the existence, location and type of AED; and
- WHEREAS, Each person or entity that acquires an AED shall ensure that the AED has been delivered by a licensed practitioner in the course of his or her professional practice upon a prescription or other order lawfully issued and complies with all applicable federal, state and local law; and
- WHEREAS, AEDs are mandatory in a place of assembly in the City of Las Vegas which has an occupant load of 1000 or more or a city building with an occupant load of 100 or more; and
- WHEREAS, Those who authorize, purchase, use or train on the use of AEDs and meet the requirements of the Texas Health and Safety Code may be granted limited liability under "Good Samaritan" statutes including, without limitation, the federal Cardiac Arrest Survival Act (42 U.S.C.A. § 238q), Chapter 779 of the Texas Health and Safety Code, Chapter 74 of the Texas Civil Practice and Remedies Code, and the Emergency Operations Chapter of the Arlington City Code; and
- WHEREAS, The Fire Department or its contractor will conduct an AED program pursuant to this Chapter; NOW THEREFORE

BE IT ORDAINED BY THE CITY COUNCIL OF THE CITY OF ARLINGTON, TEXAS:

1.

That the "Automatic External Defibrillators (AED)" Chapter of the Code of the City of Arlington, Texas, 1987, be and the same is hereby adopted so that hereafter said Chapter shall be and read as follows:

ARTICLE I

GENERAL PROVISIONS

Section 1.01 Short Title

This Chapter shall be known and cited as the Automatic External Defibrillators (AED) Chapter.

Section 1.02 Purpose

It is the purpose of this Chapter to assist in public access to AEDs. The City Council finds that the establishment of a policy and procedure regarding the placement and use of Automatic External Defibrillators (AEDs) by qualified personnel in the community can potentially save lives, and will assist in maintaining the health, safety and welfare of the community. Accordingly, the Arlington City Council hereby enacts this ordinance to address this purpose in the interest of public health and safety and to supplement federal and state law.

ARTICLE II

DEFINITIONS

Section 2.01 Definitions

"Automatic External Defibrillator or AED" means "a heart monitor and defibrillator that (i) has received approval from the United States Food and Drug Administration of its premarket notification filed under 21 U.S.C. Section 360(k), as amended; (ii) is capable of recognizing the presence or absence of ventricular fibrillation or rapid ventricular tachycardia and is capable of determining, without interpretation of cardiac rhythm by an operator, whether defibrillation should be performed; and (iii) on determining that defibrillation should be performed, automatically charges and requests delivery of an electrical impulse to an individual's heart" or the definition, as amended by Chapter 799 of the Texas Health and Safety Code.

"Church" means "a facility or area for people to gather together for public worship, religious training, or other religious activities including a temple, mosque, synagogue, convent, monastery or other structure, together with its accessory structures, including a parsonage or rectory. This use does not include home meetings or other religious activities conducted in a privately occupied residence."

"City" means all areas within the corporate limits of the City of Arlington, Texas, and its extraterritorial jurisdiction.

"Fire Department" means "the Fire Department or the City of Arlington, Texas, or any duly authorized contractor."

"Hospital" means a facility as defined by the Texas Health and Safety Code, as amended.

"Owner" means a person or entity that owns or possesses an Automatic External Defibrillator. Vendors or dealers that own or possess AED(s) solely for resale are not included as owners for the purposes of this ordinance. Hospitals, churches and governmental entities are not included in the definition of owner.

"Person" shall include an individual, firm, corporation, association, partnership, joint venture, society or other entity. Person does not include hospitals, churches, or governmental entities.

ARTICLE III

DUTIES OF OWNER

Section 3.01. Duties of Owner

Any person who presently owns or acquires an AED on or after the effective date of this ordinance, other than vendors or dealers of AEDs owning or possessing AEDs solely for resale purposes, shall:

1. Register the AED with the Fire Department and pay a registration fee as set by the Arlington City Council. The registration shall be renewed annually for each year the person owns the AED, and shall include information about AED location, and the names of all persons expected to operate the AED, and the dates of training. An annual registration fee shall also be paid by all persons owning AEDs, in the amount as set by the Arlington City Council;
2. Inspect, test, store, maintain and service the AED in accordance with all federal and state laws and regulations, and in accordance with any standards established by the City or Fire Department and the AED manufacturer;
3. Require all persons reasonably expected to operate the AED to complete training upon the use of the AED in accordance with the requirements of law including but not limited to the Texas Health and Safety Code, as it may be amended from time to time, and with any protocols and standards established by the City or the Fire Department, and to comply with all requirements of the law, protocols and standards;
4. Notify the Fire Department as soon as possible, but in no event any later than 24 hours following any use of the AED, and provide the Fire Department with information relevant to the incident, including but not limited to the date, time and location of use, name of person the AED was used upon, the printout from the AED, and the nature of other emergency response to the incident, including the name and address of any hospital, clinic or medical provider to which the person was transported following the AED use;

5. Keep and maintain records of AED training, testing, maintenance, servicing, inspection and use, and to make such records available for review by Fire Department personnel or their agents, upon request at reasonable times and places;
6. Any AED possessed and used solely for demonstration or training purposes, and which would not be operational in an actual emergency use situation, shall be exempt from the registration and fee requirements of this section. Any such AED shall be clearly marked on its exterior and readily identifiable as not appropriate for emergency use.

ARTICLE IV

EMERGENCY

Section 4.01. Emergency Contact Following AED Use

Any person who renders emergency care or treatment on a person believed to be in cardiac arrest by the use of an AED outside of a hospital setting shall activate the City emergency medical services system as soon as possible by contacting 911.

ARTICLE V

SALES

Section 5.01. Sales of AEDs

All persons selling an AED within the city, or which may reasonably be anticipated to be used within the city, shall:

1. Report the sale of the AED to the Fire Department. The information to be reported shall include the date of the sale, the manufacturer, model and serial number of the AED sold, the name and address of the seller and the purchaser, whether the AED sold is new or previously used, and, if known, the location where the AED is to be placed; and
2. Require that the purchaser provide proof that it has or will have complied with the training and other requirements of this ordinance at the time of transfer of the AED to the purchaser for deployment and use by the purchaser.

ARTICLE VI

FIRE DEPARTMENT

Section 6.01. Fire Department

The Fire Department may:

1. Develop and establish standards and protocols for the training of AED operators and AED testing, maintenance, servicing and inspection. Said standards and protocols shall be available for public inspection at the Fire Department. A copy of such standards and

protocols shall also be provided to each AED registration at the time of such registration and each renewal thereof; and

2. Receive and maintain records of the information required to be reported under this Chapter regarding AED registration, sales and incidents involving the use of an AED, and provide the location and ownership information regarding AEDs within the City in its possession to the City's emergency communications department.
3. The Fire Department may contract with an outside person for the performance of all or part of its operations under this Chapter.

ARTICLE VII

LIABILITY LIMITATIONS

Section 7.01 Governmental Immunity

This Ordinance is an exercise by the City of Arlington of its governmental functions for the protection of the public peace, health and safety; and neither the City nor agents and representatives of said City (or any individual, receiver, firm, partnership, corporation, association, trustee or any of the agents thereof, in good faith carrying out, complying with or attempting to comply with any order, rule or regulation promulgated pursuant to the provisions of this Ordinance) shall be liable for any damage sustained to persons or property as the result of said activity.

Section 7.02 Standard of Care for Emergency Action

Every officer, agent or employee of the City, and every officer, agent, or employee of an authorized provider of emergency services, including, but not limited to every unit of government or subdivision thereof, while responding to emergency calls or reacting to emergency situations, regardless of whether any declaration of emergency has been declared or proclaimed by a unit of government or subdivision thereof, is hereby authorized to act or not to act in such a manner to effectively deal with the emergency. An action or inaction is "effective" if it in any way contributes or can reasonably be thought by the provider of such emergency service to contribute to preserving any lives or property. This Section shall prevail over every other ordinance of the City and, to the extent to which the City has the authority to so authorize, over any other law establishing a standard of care in conflict with this Section. Neither the City nor the employee, agent, or officer thereof, or other unit of government or subdivision thereof or its employees, agents, or officers shall be liable for failure to use ordinary care in such emergency. It is the intent of the City Council, by passing this Ordinance, to assure effective action in emergency situations by those entrusted with the responsibility of saving lives and property by protecting such governmental units from liability, and their employees, agents, and officers from non-intentional tort liability to the fullest extent permitted by statutory and constitutional law. This Section shall be liberally construed to carry out the intent of the City Council.

ARTICLE VIII
ENFORCEMENT AND PENALTY

Section 8.01 Enforcement and Penalty

1. General. A person commits an offense if he violates by commission or omission any provision of this Chapter of the Code of the City of Arlington.
2. Registrant. A person who is required to have a registration under this Chapter commits an offense if he or she owns, operates, causes or permits to be operated an Automatic External Defibrillator without a current registration in accordance with this Chapter.
3. Penalty. A person who violates a provision of this Chapter is guilty of a separate offense for each violation committed, continued or permitted, and each offense is punishable by a fine of not more than Two Thousand and No/100 Dollars (\$2,000.00). Each day a violation continues shall be a separate offense.

2.

Any person, firm, corporation, agent or employee thereof who violates any of the provisions of this ordinance shall be guilty of a misdemeanor and upon conviction thereof shall be fined an amount not to exceed Two Thousand (\$2,000) dollars per day for each offense. Each day that a violation is permitted to exist shall constitute a separate offense.

3.

This ordinance shall be and is hereby declared to be cumulative of all other ordinances of the City of Arlington, and this ordinance shall not operate to repeal or affect any of such other ordinances except insofar as the provisions thereof might be inconsistent or in conflict with the provisions of this ordinance, in which event such conflicting provisions, if any, in such other ordinance or ordinances are hereby repealed.

4.

If any section, subsection, sentence, clause or phrase of this ordinance is for any reason held to be unconstitutional, such holding shall not affect the validity of the remaining portions of this ordinance.

5.

All of the regulations provided in this ordinance are hereby declared to be governmental and for the health, safety and welfare of the general public. Any member of the City Council or any City official or employee charged with the enforcement of this ordinance, acting for the City of Arlington in the discharge of his/her duties, shall not thereby render himself/herself personally liable; and he/she is hereby relieved from all personal liability for any damage that might accrue to persons or property as a result of any act required or permitted in the discharge of his/her said duties.

6.

Any violation of this ordinance can be enjoined by a suit filed in the name of the City of Arlington in a court of competent jurisdiction, and this remedy shall be in addition to any penal provision in this ordinance or in the Code of the City of Arlington.

7.

The caption and penalty clause of this ordinance shall be published in a newspaper of general circulation in the City of Arlington, in compliance with the provisions of Article VII, Section 15, of the City Charter. Further, this ordinance may be published in pamphlet form and shall be admissible in such form in any court, as provided by law.

8.

This ordinance shall become effective ten days after first publication as described above.

PRESENTED AND GIVEN FIRST READING on the _____ day of _____, 2004, at a regular meeting of the City Council of the City of Arlington, Texas; and GIVEN SECOND READING, passed and approved on the _____ day of _____, 2004, by a vote of _____ ayes and _____ nays at a regular meeting of the City Council of the City of Arlington, Texas.

ATTEST:

ROBERT N. CLUCK, Mayor

BARBARA G. HEPTIG, City Secretary

APPROVED AS TO FORM:
JAY DOEGEY, City Attorney

BY _____

ORDINANCE NO. _____

AN ORDINANCE AMENDING THE "**FIRE PREVENTION**" CHAPTER OF THE CODE OF THE CITY OF ARLINGTON, TEXAS, 1987, THROUGH THE AMENDMENT OF **ARTICLE I, ENTITLED GENERAL PROVISIONS, SECTION 1.03, AMENDMENTS, ADDITIONS AND DELETIONS**; PROVIDING FOR A FINE OF UP TO **\$2,000** FOR EACH OFFENSE IN VIOLATION OF THE ORDINANCE; PROVIDING THIS ORDINANCE BE CUMULATIVE; PROVIDING FOR SEVERABILITY; PROVIDING FOR GOVERNMENTAL IMMUNITY; PROVIDING FOR INJUNCTIONS; PROVIDING FOR PUBLICATION AND BECOMING EFFECTIVE TEN DAYS AFTER PUBLICATION

BE IT ORDAINED BY THE CITY COUNCIL OF THE CITY OF ARLINGTON, TEXAS:

1.

That the "**Fire Prevention**" Chapter of the Code of the City of Arlington, Texas, 1987, is hereby amended through the amendment of **Section 103**, by the addition of **Subsection 1.03.1.** and the **renumbering** of the following subsections, so that hereafter said Section shall be and read as follows:

Section 1.03 Amendments, Additions and Deletions

The adoption of the International Fire Code, as provided in Section 1.02 above, is modified and amended by the addition of the following:

1a. The addition of Subsection 102.10, to read as follows:

102.10 Emergency Medical Provisions Regarding Automatic External Defibrillators (AEDs).

- A. A health facility means a facility where the sole and primary purpose or use is providing a place for individuals to exercise by whatever means including but not limited to, use of cardio vascular exercises or machines, weights, or other means that tend to increase the heart rate of the individual engaged in exercise;
- B. A health facility shall be supplied with an AED. This requirement shall become effective on _____, 2005;
- C. AEDs shall be conspicuously located where they will be readily accessible and immediately available when needed, both for site employees and the general public;
- D. It shall be the responsibility of the owner/occupant of the facility to provide and maintain AEDs as required by 102.10; and

- E. It shall be the responsibility of the owner or occupant of the facility to provide training to designated employees on the proper use of the AEDs.

2.

Any person, firm, corporation, agent or employee thereof who violates any of the provisions of this ordinance shall be guilty of a misdemeanor and upon conviction thereof shall be fined an amount not to exceed Two Thousand (\$2000) dollars for each offense. Each day that a violation is permitted to exist shall constitute a separate offense.

3.

This ordinance shall be and is hereby declared to be cumulative of all other ordinances of the City of Arlington, and this ordinance shall not operate to repeal or affect any of such other ordinances except insofar as the provisions thereof might be inconsistent or in conflict with the provisions of this ordinance, in which event such conflicting provisions, if any, in such other ordinance or ordinances are hereby repealed.

4.

If any section, subsection, sentence, clause or phrase of this ordinance is for any reason held to be unconstitutional, such holding shall not affect the validity of the remaining portions of this ordinance.

5.

All of the regulations provided in this ordinance are hereby declared to be governmental and for the health, safety and welfare of the general public. Any member of the City Council or any City official or employee charged with the enforcement of this ordinance, acting for the City of Arlington in the discharge of his/her duties, shall not thereby render himself/herself personally liable; and he/she is hereby relieved from all personal liability for any damage that might accrue to persons or property as a result of any act required or permitted in the discharge of his/her said duties.

6.

Any violation of this ordinance can be enjoined by a suit filed in the name of the City of Arlington in a court of competent jurisdiction, and this remedy shall be in addition to any penal provision in this ordinance or in the Code of the City of Arlington.

7.

The caption of this ordinance shall be published in a newspaper of general circulation in the City of Arlington, in compliance with the provisions of Article VII, Section 15, of the City Charter. Further, this ordinance may be published in pamphlet form and shall be admissible in such form in any court, as provided by law.

8.

This ordinance shall become effective ten (10) days after first publication.

PRESENTED AND GIVEN FIRST READING on the _____ day of _____, 2004, at a regular meeting of the City Council of the City of Arlington, Texas; and GIVEN SECOND READING, passed and approved on the _____ day of _____, 2004, by a vote of _____ ayes and _____ nays at a regular meeting of the City Council of the City of Arlington, Texas.

ROBERT N. CLUCK, Mayor

ATTEST:

BARBARA G. HEPTIG, City Secretary

APPROVED AS TO FORM:
JAY DOEGEY, City Attorney

BY _____

ORDINANCE NO. _____

AN ORDINANCE AMENDING THE "**FIRE PREVENTION**" CHAPTER OF THE CODE OF THE CITY OF ARLINGTON, TEXAS, 1987, THROUGH THE AMENDMENT OF **ARTICLE I**, ENTITLED GENERAL PROVISIONS, **SECTION 1.03**, AMENDMENTS, ADDITIONS AND DELETIONS; PROVIDING FOR A FINE OF UP TO **\$2,000** FOR EACH OFFENSE IN VIOLATION OF THE ORDINANCE; PROVIDING THIS ORDINANCE BE CUMULATIVE; PROVIDING FOR SEVERABILITY; PROVIDING FOR GOVERNMENTAL IMMUNITY; PROVIDING FOR INJUNCTIONS; PROVIDING FOR PUBLICATION AND BECOMING EFFECTIVE TEN DAYS AFTER PUBLICATION

BE IT ORDAINED BY THE CITY COUNCIL OF THE CITY OF ARLINGTON, TEXAS:

1.

That the "**Fire Prevention**" Chapter of the Code of the City of Arlington, Texas, 1987, is hereby amended through the amendment of **Section 103**, by the addition of **Subsection 1.03.1.** and the **renumbering** of the following subsections, so that hereafter said Section shall be and read as follows:

Section 1.03 Amendments, Additions and Deletions

The adoption of the International Fire Code, as provided in Section 1.02 above, is modified and amended by the addition of the following:

1. The addition of Subsection 102.10, to read as follows:

102.10 Emergency Medical Provisions Regarding Automatic External Defibrillators (AEDs).

- A. A building other than a church or hospital that can accommodate more than 1000 occupants shall be supplied with an Automatic External Defibrillator (AED): This requirement shall become effective on _____, 2005;
- B. AEDs shall be conspicuously located where they will be readily accessible and immediately available when needed, for building employees and the general public;
- C. It shall be the responsibility of the owner or occupant of the facility to provide and maintain AEDs as required by this subsection; and
- D. It shall be the responsibility of the owner or occupant of the facility to provide training to employees on the proper use of the AEDs.

2.

Any person, firm, corporation, agent or employee thereof who violates any of the provisions of this ordinance shall be guilty of a misdemeanor and upon conviction thereof shall be fined an amount not to exceed Two Thousand (\$2000) dollars for each offense. Each day that a violation is permitted to exist shall constitute a separate offense.

3.

This ordinance shall be and is hereby declared to be cumulative of all other ordinances of the City of Arlington, and this ordinance shall not operate to repeal or affect any of such other ordinances except insofar as the provisions thereof might be inconsistent or in conflict with the provisions of this ordinance, in which event such conflicting provisions, if any, in such other ordinance or ordinances are hereby repealed.

4.

If any section, subsection, sentence, clause or phrase of this ordinance is for any reason held to be unconstitutional, such holding shall not affect the validity of the remaining portions of this ordinance.

5.

All of the regulations provided in this ordinance are hereby declared to be governmental and for the health, safety and welfare of the general public. Any member of the City Council or any City official or employee charged with the enforcement of this ordinance, acting for the City of Arlington in the discharge of his/her duties, shall not thereby render himself/herself personally liable; and he/she is hereby relieved from all personal liability for any damage that might accrue to persons or property as a result of any act required or permitted in the discharge of his/her said duties.

6.

Any violation of this ordinance can be enjoined by a suit filed in the name of the City of Arlington in a court of competent jurisdiction, and this remedy shall be in addition to any penal provision in this ordinance or in the Code of the City of Arlington.

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The caption of this ordinance shall be published in a newspaper of general circulation in the City of Arlington, in compliance with the provisions of Article VII, Section 15, of the City Charter. Further, this ordinance may be published in pamphlet form and shall be admissible in such form in any court, as provided by law.

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PRESENTED AND GIVEN FIRST READING on the _____ day of _____, 2004, at a regular meeting of the City Council of the City of Arlington, Texas; and

GIVEN SECOND READING, passed and approved on the _____ day of _____, 2004, by a vote of _____ ayes and _____ nays at a regular meeting of the City Council of the City of Arlington, Texas.

ATTEST:

ROBERT N. CLUCK, Mayor

BARBARA G. HEPTIG, City Secretary

APPROVED AS TO FORM:
JAY DOEGEY, City Attorney

BY _____